

Dockets Management Branch (HFA-305)
Division of Management Systems and Policy
Office of Human Resources and Management Services
Food and Drug Administration
5603 Fishers Lane, Room 1061
Rockville, MD 20852

1902 '00 APR 14 10:45

Re: Docket No. 99N-4491, FDA's Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals and Reprocessing and Reuse of Single-Use Devices: Review Prioritization Scheme

Dear Ladies and Gentlemen:

We are writing in response to the FDA's two draft guidance documents: Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals and Reprocessing and Re-use of Single-Use Devices: Review Priorities Scheme. As professionals in the infection control and sterile processing field, we belong to a community of professionals who have been instrumental in the development of safe and effective techniques for reprocessing medical devices. This issue is of great importance to our profession and is critical to the delivery of health care.

We are very encouraged by the FDA's decision to take action on this issue to ensure and enhance patient safety. The FDA's risk-based categorization scheme is a sound approach to regulatory oversight. Factors such as risk of infection and device performance are critical in determining whether or not reprocessing is appropriate, safe and effective. We would like to take this opportunity to respond to specific issues raised in the draft documents, as follows:

We applaud FDA for recommending that opened but unused medical devices be exempt from the regulatory guidance. There is no scientific evidence that would establish a public health risk with the reprocessing of these devices. Since they have not, by definition, been previously used on a patient, the reprocessing of these devices do not raise the same level of concern as the reprocessing of devices that have been used on a patient. In addition to exempting opened but unused devices, the FDA should require Original Manufacturers(OEMs) to provide special sterilization instructions as part of the labeling requirement to ensure that the proper method of sterilization is used on those devices whose sterility may be breached and would require re-sterilization.

Exempting non-acute facilities such as ambulatory care centers, clinics, and physicians offices from regulatory guidance is counter-productive to the FDA's efforts to ensure and enhance patient safety associated with the re-use of SUD's. These health care facilities often times lack the necessary resources and protocols to ensure safe and effective reprocessing of single-use items. We strongly encourage the FDA to phase-in enforcement of the guidelines for all health care facilities that reprocess, not just hospitals.

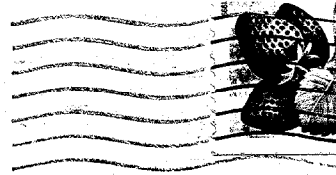
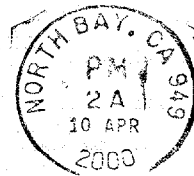
We urge the FDA to seek uniformity from OEM's in the process and manner in which devices are labeled. There are no standards in place which guide multi-use vs. single-use labeling. An OEM should not be permitted to label a device for single-use if it is aware of safe and effective reprocessing and sterilization procedures. The device label should include the number of times the device will perform without failure as validated by the OEM. The release of FDA's final guidance documents should be delayed until the FDA addresses this labeling issue.

Furthermore, if hospitals and third party reprocessors are expected to utilize the flow chart as outlined in the Review Prioritization Scheme, the materials, coatings and components of a device must be known. And finally, in all cases, the OEMs should be required to provide instructions for acceptable, validated methods of sterilization and/or resterilization for all devices.

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